

SEP 29 1998

1C983241

KAMIYA BIOMEDICAL COMPANY

910 Industry Drive, Seattle, WA 98188 USA

TEL: (206) 575-8068

FAX: (206) 575-8094

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K 983241

Date: September 10, 1998

Submitted by: Colin Getty
KAMIYA BIOMEDICAL COMPANY
910 Industry Drive, Seattle WA 98188
TEL: 206-575-8068; FAX: 206-575-8094

Product: ASO/CRP/RF Control

The KAMIYA ASO/CRP/RF Control is a lyophilized, human serum-based, assayed control for use as a consistent test sample of known concentration for monitoring the performance of ASO, CRP, and RF immunoturbidimetric assays.

Two levels of the KAMIYA ASO/CRP/RF Control are provided. The human serum used to manufacture this product is tested and found negative for the presence of HBsAg and antibody to HCV and HIV. The assigned CRP values are traceable to the CAP/BCR/IFCC Reference Preparation for Proteins in Human Serum. The assigned RF values are traceable to the WHO International Reference Preparation of Rheumatoid Arthritis Serum. The assigned ASO values are traceable to the Japanese National Standard for ASO.

This product is stable for at least 1 year (unopened) and 2 weeks (after reconstitution).

The safety and effectiveness of the KAMIYA ASO/CRP/RF Control is demonstrated by its substantial equivalence to the Sigma Immunology Control (K851202). The KAMIYA ASO/CRP/RF Control shows similar within run and between day precision and reaction characteristics for the 3 analytes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 29 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Colin Getty
Kamiya Biomedical Company
910 Industry Drive
Seattle, Washington 98188

Re: K983241
Trade Name: ASO/CRP/RF Control
Regulatory Class: I
Product Code: JJY
Dated: September 9, 1998
Received: September 15, 1998

Dear Mr. Getty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

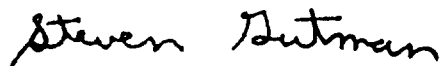
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K983241

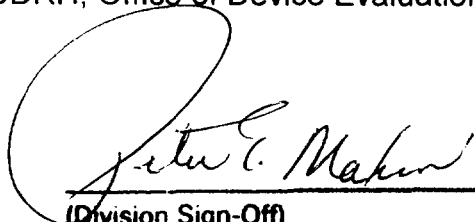
Device Name: ASO/CRP/RF Controls

Indications For Use:

As a consistent test sample of known concentration for monitoring the performance of ASO, CRP, and RF immunoturbidimetric assays.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983241

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

Optional Format 1-2-96)